

Traditional 510(k) Submission MAY 28 2014

LifeBorne Infant Resuscitator – March 18, 2014

510(k) SUMMARY

Submitter Information:

International Biomedical
8206 Cross Park Drive
Austin, TX 78754
U.S.A.

Regulatory Affairs Contact:

Amy Pieper
Director of Regulatory Affairs
(512) 873-0033 - phone
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Date Summary Prepared:

March 18, 2014

Device Identification:

Trade Name: LifeBorne Infant Resuscitator
Common Name: Ventilator, Emergency Gas Powered (Resuscitator)
Regulatory Class: II
Regulation: 868.5925
Product Code: BTL
Panel: Anesthesiology

Predicate Device:

GE – Giraffe and Panda T-Piece Resuscitation System – k070210
Fisher & Paykel – NeoPuff – k892885

Device Description:

The resuscitation system provides the basic equipment required for pulmonary resuscitation of neonatal infants. The LifeBorne Infant Resuscitator is a gas powered emergency resuscitation system. It is intended to be used inside the hospital by trained medical professionals to provide precise FIO₂ delivery, manual ventilation, and emergency airway clearance as established by resuscitation guidelines to neonates and infants weighing less than 10 kg (22 lb).

Intended Use:

The LifeBorne Infant Resuscitator is intended to provide the basic equipment required for pulmonary resuscitation of neonatal infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the neonatal infant.

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Functional Description and Technological Characteristics:

The LifeBorne Infant Resuscitation System incorporates the following components for neonatal resuscitation:

- Venturi vacuum device for suctioning airways (no 510k)
- Vacuum gauge for monitoring suction pressures (no 510k)
- Medical blender to mix air and oxygen to a precise FIO₂ (k883038 or k925982)
- Flowmeters for the delivery of oxygen or air/oxygen mixtures (no 510k)
- Peak Inspiratory Pressure (PIP) control to set the maximum pressure delivered during an inspiratory phase of a manual breath (no 510k)
- Peak End Expiratory Pressure (PEEP) control located on a provided T-piece circuit to set the maximum pressure during the expiratory phase of a manual breath (k093913)
- An airway pressure manometer to monitor both PIP and PEEP airway pressure (no 510k)

Substantial Equivalence:

The LifeBorne Infant Resuscitator described in this submission is, in our opinion, substantially equivalent to the predicate device, in regards to intended use and safety and effectiveness. The intended use of the LifeBorne Infant Resuscitator is identical to the intended use of the predicate k070210.

	Proposed LifeBorne Infant Resuscitator	Predicate k070210 GE Giraffe and Panda	Predicate k892885 F&P NeoPuff
Indications for Use	The LifeBorne Infant Resuscitator is intended to provide the basic equipment required for pulmonary resuscitation of neonatal infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the neonatal infant.	The T-piece resuscitation system provides the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and or manual ventilation to the infant.	Manually operated, gas powered resuscitator which provides controlled and accurate resuscitation of newborn babies.
Environment for Use	Hospital, delivery suites, nursery, ICU	Hospital, delivery suites, nursery, ICU	Hospital, delivery suites, nursery, ICU
Patient Population	Infant < 10 kg	Infant < 10 kg	Infant < 10 kg
Patient Connection	Face mask; ET tube	Face mask; ET tube	Face mask; ET tube
Air/Oxygen Mixture	21-100%	21-100%	Not specified
Gas Flow Source	Wall gas or cylinder	Wall gas or cylinder	Wall gas or cylinder
Manometer Range	-10 to 80 cm H ₂ O	-10 to 80 cm H ₂ O	-20 to 80 cm H ₂ O

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Peak Inspiratory Pressure (PIP)	Max 45 +/- 5 cm H2O	Max 45 +/- 5 cm H2O	2 – 80 cm H2O
Positive End Expiratory Pressure (PEEP)	0-6 cm H2O	0-6 cm H2O	1-25 cm H2O, depending on flowrate
Vacuum Pressure Range	0 – 150 mmHg, negative pressure	0 – 150 mmHg, negative pressure	N/A – suction not available
Maximum gas flow rate	15 LPM	15 LPM	15 LPM
Maximum pressure relief	55 cm H2O	55 cm H2O	40 cm H2O
Features: Venturi Vacuum Device	Present, same as predicate	Present	N/A
Features: Vacuum gauge	Present, same as predicate	Present	N/A
Features: Integrated Medical Blender	Present, same as predicate	Present	Non integrated, but available
Features: Flowmeters for delivery of gas	Present, same as predicate	Present	Not integrated, but available
Features: PIP control	Present, same as predicate	Present	Present
Features: PEEP control	Present, same as predicate	Present	Present
Features: Airway pressure manometer	Present, same as predicate	Present	Present

Performance Testing:

Pulmonary resuscitation of infants includes well established clinical practices; clinical testing is not necessary to support safety and effectiveness. Conformance of the LifeBorne Infant Resuscitation System to performance specifications has been established through bench testing.

TEST	TEST REQUIREMENTS	SUMMARY OF RESULTS
Valve Function after Vomitus	The proper function of the circuit shall be verified within 20 seconds of becoming disabled by vomitus. Function is verified by verifying flow valve accuracy.	Passed.
Inspiratory Resistance	Pressure generated at the patient connection port during expiration should not exceed -5 cmH2O with inspiratory airflow set to 6 L/min.	Passed.
Expiratory Resistance	Pressure generated at the patient connection port during expiration should not exceed 5 cmH2O with expiratory airflow set to 6 L/min.	Passed.
Dead Space	The deadspace volume of the T-Piece circuit should be less than 7 mL.	Passed.

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FIO2 accuracy	The proper function of the FIO2 adjustment knob shall be verified by comparing the FIO2 setting value with the output oxygen concentration. Values shall be within 5%.	Passed.
Primary and Secondary Flow Valve – Peak Flow	The proper function of the primary and secondary flow valves shall be verified by comparing the flow setting with the actual measured output flow.	Passed.
Airway Manometer Accuracy	The proper function of the airway manometer shall be verified by comparing the pressure readings with the actual measured output pressure.	Passed.
VOC Testing	The device should not add volatile organic compounds (VOCs) to the output gas delivered to the patient.	Passed
Particulate Analysis	The output of particulate matter sizes 2.5 microns or less are no more than 12 micrograms/cubic meter of air at one atmospheric pressure.	Passed

The LifeBorne Infant Resuscitator met all the performance requirements as outlined above and thus can be found to be substantially equivalent to the predicate devices.

Conclusion:

In regards to intended use and technology the LifeBorne Infant Resuscitator is substantially equivalent to the listed predicates. Any differences between the LifeBorne Infant Resuscitator and the predicates do not raise any new questions of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 28, 2014

International Biomedical, Ltd.
Amy Pieper
Director of Regulatory Affairs
8206 Cross Park Drive
Austin, TX 78754

Re: K140707

Trade/Device Name: LifeBorne Infant Resuscitator
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered emergency ventilator
Regulatory Class: Class II
Product Code: BTL
Dated: March 18, 2014
Received: March 24, 2014

Dear Ms. Pieper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

Device Name
LifeBorne Infant Resuscitator

Indications for Use (Describe)

The LifeBorne Infant Resuscitator is intended to provide the basic equipment required for pulmonary resuscitation of neonatal infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the neonatal infant.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Anya C. Harry -S
2014.05.23
10:09:29 -04'00'

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